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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,863	01/24/2006	Yoshitomo Takaishi	D3301- 00160	7327

8933 7590 06/05/2009

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IP DEPARTMENT
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EXAMINER	
LEE, JOHN W	

ART UNIT	PAPER NUMBER
2624	

MAIL DATE	DELIVERY MODE
06/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,863	TAKAISHI, YOSHITOMO	
	Examiner	Art Unit	
	JOHN Wahnkyo LEE	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060410 and 20080128* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Claims 1-17 are pending including amended claims 4-10 and added claims 12-17.

Information Disclosure Statement

1. Initialed and dated copies of Applicant's IDS form 1449, Paper No. 20060410 and 20080128 are attached to the instant Office action.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 11 is rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent[1] and recent Federal Circuit decisions[2] indicate that a statutory "process" under 35 U.S.C. 101 must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform underlying subject matter nor positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

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[1] *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

[2] *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

First of all, the steps in this claim can be performed manually without the use of a particular machine. The claim could conceivably be interpreted to mean that someone can manually notice the gradation of the X-ray image including the picture of the specimen, correct the X-ray image using a pen or some other office supply and evaluate the image. So, the claims are not tied to a machine or a structural embodiment.

Moreover, there is no physical object transformed physically, but X-ray image is a data that represents the specimen, which is modified by correcting the gradation of it. However, the claim does not disclose any depiction of modified data as external representation of physical object such as displaying. So, the claim does not also qualify as a transformation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (WO 02/30283 A2).

Regarding claim 1, Lang discloses a bone mineral density evaluation system for evaluating a bone mineral density from an X-ray picture (page 21, lines 9-10, “evaluate bone density and structure data in the image”) of a mandible (page 18, line 8), said X-ray picture containing a picture of a specimen (page 18, line 8, “trabecular”) disposed beside a picture of said mandible, said system comprising: detecting means for

detecting a gradation of said picture (page 16, lines 5-14, "… detector system or a storage plate for digital x-ray imaging using) of said specimen (page 18, line 8, "trabecular"); correcting means for correcting the gradation of said X-ray picture so as to make the result of detection by said detecting means comply with a standard value (page 21, line 9, "correct for soft tissue measurements"); and evaluating means for evaluating the bone mineral density on the basis of the corrected gradation as corrected by said correcting means (page 21, lines 9-10, "evaluate bone density and structure of the image").

Regarding claim 2, Lang discloses wherein said evaluating means making evaluation on the basis of the corrected gradation of a particular region of said X-ray picture (page 32, line 2, "anatomical region").

Regarding claim 4, Lang discloses wherein said detecting means detecting a gradation of a particular portion of said picture of said specimen (page 32, lines 2-4 "anatomical region can be selected from the group consisting of an edge of the mandible, and edge of the maxilla, an edge of a tooth, valleys or grooves in any of these structures or combinations thereof.").

Regarding claim 5, Lang discloses the gradation of said picture of said specimen differing from portion to portion thereof (page 18, lines 19-20, "attenuate the beam differently and thus change the effective x-ray beam spectrum") and said detecting means detecting one or both of average and deviation of the gradation of said picture of said specimen (table 1; pages 38-39, "mean pixel intensity" and "variance of pixel intensity").

Regarding claim 6, Lang discloses further comprising setting means for setting said standard value (page 31, lines 1-9, "correction factors).

Regarding claim 7, Lang discloses wherein said standard value being set based on a result of detection by said detecting means of a particular X-ray picture (page 31, lines 5-8, "Such correction factors will take into account one or more of a wide variety of influences (e.g., soft tissue thickness, region from which the data is extracted and the like) that can alter apparent density or structure information on the x-ray image.").

Regarding claim 9, Lang discloses wherein said evaluating means including judging means for judging said bone mineral density on the basis of said corrected gradation (page 46, lines 16-20, "… analyze bone mineral density … determining if the subject has a bone-related condition such as osteoporosis").

Regarding claim 10, Lang discloses further comprising output means for providing together a plurality of evaluation results provided by said evaluation means for respective ones of a plurality of X-ray pictures (page 42, lines 1-3, "variations in soft tissue thickness can be significant in analyzing and evaluating bone density and bone structures in x-rays.").

Regarding claim 11, claim 11 is analogous and corresponds to claim 1. See rejection of claim 1 for further explanation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 3, 12-14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (WO 02/30283 A2).

Regarding claim 3, Lang discloses all the previous claim limitation except the one specified in claim 3. It is true that Lang does not explicitly disclose said particular region including a region corresponding to an alveolar bone portion around a first premolar. However, Lang discloses an anatomical region, which is a particular region, being selected from the group consisting of an edge of the mandible, and edge of the maxilla, an edge of a tooth, valleys or grooves in any of these structures or combinations thereof (page 32, lines 2-4) and figures of teeth or the convexity/concavity of the mandible as region of interest (Figs. 13 and 14). An alveolar bone portion around a first premolar is just a region of the tooth, and the applicant does not provide any advantage by including it in the invention. In other words, an alveolar bone portion around a first premolar is just a data that will be a matter of design selection or choice. Moreover, a person of ordinary skill in the art will be able to detect the alveolar bone portion around a first premolar if the person of ordinary skill in the art can detect the anatomical regions such as an edge of the mandible, and edge of the maxilla, an edge of a tooth, valleys or grooves in any of these structures or combinations thereof.

Therefore, it would have been obvious to a person of ordinary skill in the art to try to include alveolar bone portion around a first premolar as one of the anatomical region disclosed by Lang in attempt to provide a wide variety of data of regions for the improvement of X-ray imaging system, which has the function of the bone mineral

density evaluation system, of Lang, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. Because an alveolar bone portion around a first premolar is just a region of the tooth, which Lang discloses as one of the anatomical region, it would have been obvious to include alveolar bone portion around a first premolar as one of the anatomical region.

Regarding claim 12, Lang discloses a bone mineral density evaluation system for evaluating a bone mineral density from an X-ray picture (page 21, lines 9-10, "evaluate bone density and structure data in the image") of a mandible (page 18, line 8), said X-ray picture containing a picture of a specimen (page 18, line 8, "trabecular") disposed beside a picture of said mandible, said system comprising: detecting means for detecting a gradation of said picture (page 16, lines 5-14, "… detector system or a storage plate for digital x-ray imaging using) of said specimen (page 18, line 8, "trabecular"); correcting means for correcting the gradation of said X-ray picture so as to make the result of detection by said detecting means comply with a standard value (page 21, line 9, "correct for soft tissue measurements"); and evaluating means for evaluating the bone mineral density on the basis of the corrected gradation as corrected by said correcting means (page 21, lines 9-10, "evaluate bone density and structure of the image"), wherein said evaluating means making evaluation on the basis of the corrected gradation of a particular region of said X-ray picture (page 32, line 2, "anatomical region"), and wherein: the gradation of said picture of said specimen differing from portion to portion thereof (page 18, lines 19-20, "attenuate the beam differently and thus change the effective x-ray beam spectrum"), and said detecting

means detecting one or both of average and deviation of the gradation of said picture of said specimen (table 1; pages 38-39, “mean pixel intensity” and “variance of pixel intensity”). However, Lang does not explicitly disclose said particular region including a region corresponding to an alveolar bone portion around a first premolar. Lang discloses an anatomical region, which is a particular region, being selected from the group consisting of an edge of the mandible, and edge of the maxilla, an edge of a tooth, valleys or grooves in any of these structures or combinations thereof (page 32, lines 2-4) and figures of teeth or the convexity/concavity of the mandible as region of interest (Figs. 13 and 14). An alveolar bone portion around a first premolar is just a region of the tooth, and the applicant does not provide any advantage by including it in the invention. In other words, an alveolar bone portion around a first premolar is just a data that will be a matter of design selection or choice. Moreover, a person of ordinary skill in the art will be able to detect the alveolar bone portion around a first premolar if the person of ordinary skill in the art can detect the anatomical regions such as an edge of the mandible, and edge of the maxilla, an edge of a tooth, valleys or grooves in any of these structures or combinations thereof.

Therefore, it would have been obvious to a person of ordinary skill in the art to try to include alveolar bone portion around a first premolar as one of the anatomical region disclosed by Lang in attempt to provide a wide variety of data of regions for the improvement of X-ray imaging system, which has the function of the bone mineral density evaluation system, of Lang, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. Because an alveolar bone

portion around a first premolar is just a region of the tooth, which Lang discloses as one of the anatomical region, it would have been obvious to include alveolar bone portion around a first premolar as one of the anatomical region.

Regarding claim 13, claim 13 is analogous and corresponds to claim 6. See rejection of claim 6 for further explanation.

Regarding claim 14, claim 14 is analogous and corresponds to claim 7. See rejection of claim 7 for further explanation.

Regarding claim 16, claim 16 is analogous and corresponds to claim 9. See rejection of claim 9 for further explanation.

Regarding claim 17, claim 17 is analogous and corresponds to claim 10. See rejection of claim 10 for further explanation.

8. Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (WO 02/30283 A2) in view of Inoue (US 6,819,794 B2).

Regarding claim 8, Lang discloses all the previous claim limitations and evaluating means including display means for displaying said corrected gradation (page 45, line 8, “kit comprises computer”). However, Lang does not disclose displaying in the form of histogram. Instead of Lang, Inoue discloses displaying in the form of histogram (Fig. 3-307, "histogram”; col. 8, lines 24-28).

It would have been obvious to one of ordinary skill in the art to include displaying the histogram disclosed by Inoue to improve the evaluation steps of the X-ray imaging system of Lang for the predictable results of allowing the user to visually detect the

range, minimum & maximum, clusters and outliers easily, which can help the user to manipulate the data more efficiently and easier.

Regarding claim 15, claim 15 is analogous and corresponds to claim 8. See rejection of claim 8 for further explanation.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN Wahnkyo LEE whose telephone number is (571)272-9554. The examiner can normally be reached on Monday - Friday (Alt.) 7:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571) 272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHARLES KIM/
Primary Examiner, Art Unit 2624
June 4, 2009

/John Wahnkyo Lee/
Examiner, Art Unit 2624